CADTH

CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

Foot Drop Stimulators for Foot Drop: A Review of Clinical, Cost-Effectiveness, and Guidelines

Service Line:	Rapid Response Service
Version:	1.0
Publication Date:	November 21, 2018
Report Length:	13 Pages

CADTH

Authors: Chuong Ho, Lorna Adcock

Cite As: Foot drop stimulators for foot drop: A review of clinical-, cost-effectiveness and guidelines. Ottawa: CADTH; 2018 Jan. (CADTH rapid response report: summary with critical appraisal).

ISSN: 1922-8147 (online)

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Context and Policy Issues

As of 2013, about 741,800 Canadian adults aged 20 and older were living with the effects of a stroke in 2013.[1] One of the most prominent and disturbing neurological deficits resulting from strokes is foot drop, which is characterized by the inability to lift the toes completely off the ground during the swing phase of walking. While foot drop is frequently present in those who have experienced a stroke, it is also a manifestation in other neurological conditions such as cerebral palsy and multiple sclerosis, as well as spinal cord and brain injuries.[2,3] Foot drop primarily affects walking speed that is usually categorized from less than 0.4 m/second (household walking only) to less than 0.79 m/second (limited community walking).[4]

Foot drop is usually treated with orthotics such as ankle foot orthosis (AFO), rehabilitation with physical therapy, or surgery.[2] Nerve stimulation, using myoelectric orthotics such as functional electrical stimulators (FES), is a rehabilitation technique intended to enhance movement or function of organs, muscles, and extremities by applying electrical currents to peripheral nerves, and is used during rehabilitation for adults and children with neurologic dysfunction such as foot drop.[5] FES systems commonly use single-pad transcutaneous electrodes with the wireless control of stimulation through an in-shoe sensor or tilt sensor, but novel multi-pad electrodes are also used.[6] Foot drop is usually assessed by outcomes that are categorized into Functional Outcomes using a tool such a 10-m walk test to measure walking speed, or Body Functions & Structures outcomes that measure physical exertion, mobility of the lower extremity, balance disability and activities of daily living using tools such as Timed Up and Go, Borg Scale, Modified Emory Functional Ambulation Profile (mEFAP), modified Barthel Index (mBI), Physiologic Cost Index (PCI), lower extremity Fugl-Meyer Assessment (FMA), Expanded Disability Status Scale (EDSS), Fatigue Severity Scale (FSS), Falls Efficacy Scale (FEScale), and Berg Balance Scale (BBS).[7]

FES has been shown to be effective in improving many aspects of walking in patients with foot drop caused by various neurological conditions,[8-15] but the effectiveness of FES compared to other treatment modalities is not clear. This Rapid Response report aims to review the clinical and cost-effectiveness of FES compared to other therapies such AFO, rehabilitation, and surgery for the treatment of patients with foot drop.

Research Questions

1. What is the clinical-effectiveness of myoelectric orthotics for patients with foot drop?
2. What is the cost-effectiveness of myoelectric orthotics for patients with foot drop?
3. What are the evidence-based guidelines regarding myoelectric orthotics for patients with foot drop?

Key Findings

In people with foot drop caused by stroke, functional electrical stimulators (FES) seems to lead to the same functional outcome (walking speed) and Body Functions & Structures outcomes compared to ankle and foot orthosis (AFO), and the combination

of FES and rehabilitation seems to improve walking speed compared to rehabilitation alone. FES may significantly reduce the perceived exertion compared to AFO in those with multiple sclerosis-related foot drop. There were no relevant cost-effectiveness and guidelines on the use of FES for foot drop identified.

Methods

A limited literature search was conducted on key resources including Ovid Medline, PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases and a focused Internet search. No methodological filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was limited to English language documents published between January 1, 2013 and October 24, 2018.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Patients with foot drop (e.g., due to palsy, spinal cord injury, MS, stroke)
Intervention	Myoelectric stimulator, neuroprotheses, functional electric stimulators
Comparator	Q1-2: Control group, other foot drop treatments (e.g., other orthotics, physical therapy, surgery, etc.) Q3: No comparator
Outcomes	Q1: Clinical effectiveness (e.g. change in symptoms, psychological benefits) Q2: Cost-effectiveness Q3: Guidelines
Study Designs	Heath technology assessments, systematic reviews, meta-analyses, randomized controlled trials (RCTs), non-RCTs, cost effectiveness evaluation studies, evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications were already reported in the included SRs, or were published prior to 2013.

Critical Appraisal of Individual Studies

The included systematic reviews, clinical studies and cost studies were assessed using the AMSTAR I2,[16] and Downs & Black[17] checklists, respectively. Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 306 citations were identified in the literature search. Following screening of titles and abstracts, 277 citations were excluded and 29 potentially relevant reports from the electronic search were retrieved for full-text review. Two potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, 27 publications were excluded for various reasons, while four publications (two SRs, two clinical studies) met the inclusion criteria and were included in this report. Appendix 1 presents the PRISMA flowchart of the study selection.

Summary of Study Characteristics

The literature search identified two relevant systematic reviews[18,19] and two clinical studies.[20,21]

Study design

One included review performed systematic review with meta-analysis of RCTs (search date not indicated),[18] and one was narrative systematic review of RCTs, with literature search up to May 2014.[19] One clinical study was a single-blind RCT,[20] and one was a cross-over unblinded RCT (both devices were used in each visit, and patients randomly assigned to which device to use first).[21]

Country of origin

One systematic review was performed in UK,[18] and one in the US.[19] One clinical study was conducted in Serbia and Spain,[20] and one in the US.[21]

Patient population

One systematic review selected studies that included patients of any age with foot drop caused by mostly stroke (n = 450), and cerebral palsy (n = 14)[18] and one systematic review selected studies that included patients of all age with foot drop caused by stroke.[19] The clinical studies were included adult patients with foot drop caused by stroke,[20] and multiple sclerosis.[21]

Interventions and comparators

The systematic reviews[18,19] compared different FES to AFO. One clinical study compared FES (FESa) plus conventional rehabilitation (physiotherapy 60 minutes a day, five days a week, for four weeks) to rehabilitation alone,[20] and one clinical study compared FES (WalkAide) to AFO.[21]

Outcomes

One systematic reviews reported 10-m walking speed as the primary functional outcome,[18] and one systematic review reported 10-m walking speed and various Body Functions & Structures outcomes (mEFAP, PCI, FMA and BBS).[19] One clinical study reported 10-m walking speed and Body Functions Outcomes (FMA, BBI, mBI, EDSS, FSS, FEScale),[20] and one study reported physical exertion, walking speed, caloric expenditure and metabolic efficiency.[21] Details on most Body Functions & Structures outcomes and their clinically meaningful difference were not provided,

Characteristics of the included studies are detailed in Appendix 2.

Summary of Critical Appraisal

The included SRs[18,19] provided an a priori design and performed a systematic literature search; procedures for the independent duplicate selection and data extraction of studies were in place, a list of included studies and characteristics were provided, and conflict of interests stated. Quality assessment of the included studies was performed using the Cochrane Risk of Bias Assessment or the PEDro tool, and used in formulating conclusions. A list of excluded studies was not provided, and publication bias was not assessed in both SRs. Heterogeneity in interventions and comparators among the primary studies may have affected the accuracy and reliability of the findings of the reviews; the results from the SRs should be interpreted with caution.

The included clinical studies[20,21] had clearly described hypotheses, method of selection from source population and representation of the study population, main outcomes, interventions, patient characteristics, and main findings. Estimates of random variability and actual probability values were provided with appropriate methods. In one trial, patients were blinded, and sample size was calculated to have enough power to detect clinically important effects,[20] while both patients and assessors were not blinded, and sample size not calculated in one trial, rendering the findings more prone to bias.[21]

Details of the critical appraisal of the included studies are presented in Appendix 3.

Summary of Findings

The main findings of the included studies are presented in Appendix 2.

Clinical effectiveness of myoelectric orthotics

Foot drop due to stroke

Authors of one systematic review withmeta-analysis[18] found there were no statistically significant differences on 10-meter walking speed between FES and AFO after 4 to 6 weeks of use in a group of patients where the majority had stroke (450 who had had a stroke patients and 14 with cerebral palsy). Similarly, in the sub-group analysis that considered those with stroke only, differences were not statistically significant. The authors concluded that FES and AFO had the same therapeutic effect on patients with central nervous system conditions such as stroke after 4 to 6 weeks of use.

The results of one systematic review with narrative synthesis[19] showed that in the trials that included participants who had stroke-related foot drop, there were no statistically significant differences on 10-meter walking speed, Time Up and Go, mEFAP, and FMA between FES and AFO. Differences between FES and AFO were inconsistently significant on BBS and PCT among trials. More patients preferred FES over AFO (statistical difference not reported). The authors concluded that the effect of FES and AFO on walking speed was equivalent after up to 30 weeks of use.

One RCT that included participants with stroke-related foot drop[20] showed that FES plus rehabilitation therapy increases in walking speed compared to rehabilitation alone were statistically significant, but the differences between the two groups were not statistically significant in Body Functions & Structures Outcomes FMA, BBS, and

MI. The authors concluded that FES combined with rehabilitation was more effective than rehabilitation alone in improving walking speed.

Patients with foot drop due to multiple sclerosis

Data from one cross-over RCT that included participants with multiple sclerosis-related foot drop[21] showed that FES was associated with a statistically significant reduction in the perceived exertion compared to AFO. There were no statistically significant differences between the 2 groups in walking speed, caloric expenditure, and metabolic efficiency. The authors concluded that patients with FES reported decreased exertion level compared to AFO.

Cost-Effectiveness of myoelectric orthotics

There were no relevant studies identified that met the pre-specified criteria on the cost-effectiveness of myoelectric orthotics for patients with foot drop.

Guidelines

There were no relevant evidence-based guidelines identified that met the pre-specified criteria regarding myoelectric orthotics for patients with foot drop.

Limitations

Most evidence on the comparative effectiveness of FES was relevant to patients with foot drop caused by stroke, with limited evidence on multiple sclerosis, and no evidence found for other neurological conditions. Heterogeneity in interventions and comparators among the primary studies may have affected the accuracy and reliability of the findings of the reviews included in this report.

Conclusions and Implications for Decision or Policy Making

Evidence from systematic reviews showed that the use of FES and AFO led to equivalent walking speed in patients with foot drop caused by stroke. There were also no statistically significant differences among the two groups in terms of Body Functions & Structures outcomes, though patients may prefer FES use over AFO. FES combined with rehabilitation was found to be more effective than rehabilitation alone on walking speed for those with stroke-related foot drop in one RCT. For participants with multiple sclerosis, data from one cross-over RCT found that FES statistically reduced the perceived exertion and equivalent walking speed, caloric expenditure and metabolic efficiency compared to AFO.

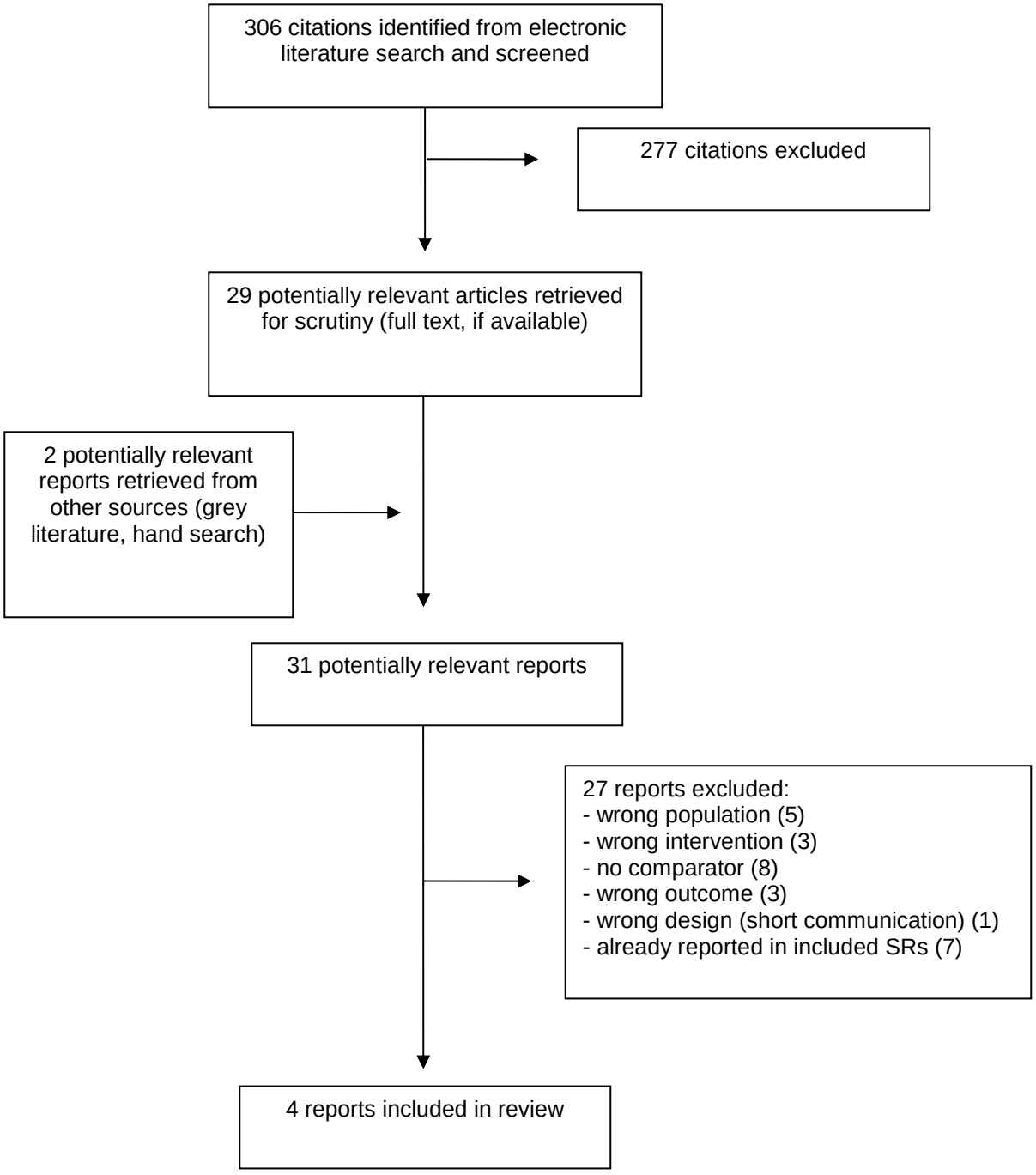
A UK cost study that did not include a comparator showed that FES was a practical, long term and cost-effective for the correction of drop foot.[22] The study showed that 26% of patients with foot drop caused by central nervous system conditions such as stroke, multiple sclerosis, spinal cord injury, and cerebral palsy still used FES after a mean of 11 years. Mean treatment cost per patient was £3,095 in 2012, with a mean treatment cost per quality-adjusted-life-year (QALY) of £15,406 (willingness to pay threshold used by the National Institute for Health and Clinical Excellence – NICE - is £20,000 per QALY).

Controlled studies comparing the clinical and cost-effectiveness of FES to other treatment modalities, and evidence-based guidelines on the use of FES on patients with foot drop caused by various neurological conditions are needed to reduce uncertainty regarding the use of myoelectric foot orthotics for the management of foot drop.

References

1. Government of Canada. Stroke in Canada. 2016; https://www.canada.ca/en/public-health/services/publications/diseases-conditions/stroke-in-canada.html. Accessed 2018 Nov 20.
2. Mayo Clinic. Foot drop. 2017; https://www.mayoclinic.org/diseases-conditions/foot-drop/symptoms-causes/syc-20372628. Accessed 2018 Nov 20.
3. Ho CH, Triolo RJ, Elias AL, Kilgore KL, DiMarco AF, Bogie K, et al. Functional electrical stimulation and spinal cord injury. Phys Med Rehabil Clin N Am. 2014;25(3):631-654, ix.
4. Perry J, Garrett M, Gronley JK, Mulroy SJ. Classification of walking handicap in the stroke population. Stroke. 1995;26(6):982-989.
5. Wilder RP, Wind TC, Jones EV, Crider BE, Edlich R. A review on functional electrical stimulation for a dropped foot. J Long Term Eff Med Implants. 2017;27(2-4):267-277.
6. Melo PL, Silva MT, Martins JM, Newman DJ. Technical developments of functional electrical stimulation to correct drop foot: sensing, actuation and control strategies. Clin Biomech. 2015;30(2):101-113.
7. Andreopoulou G, Mercer TH, van der Linden ML. Walking measures to evaluate assistive technology for foot drop in multiple sclerosis: A systematic review of psychometric properties. Gait Posture. 2018;61:55-66.
8. Renfrew ML, Flowers P, Lord AC, Rafferty D, McFadyen AK, Bowers R, et al. An exploration of the experiences and utility of functional electrical stimulation for foot drop in people with multiple sclerosis. Disabil Rehabil. 2018:1-9.
9. Miller L, McFadyen A, Lord AC, Hunter R, Paul L, Rafferty D, et al. Functional electrical stimulation for foot drop in multiple sclerosis: A systematic review and meta-analysis of the effect on gait speed. Arch Phys Med Rehabil. 2017;98(7):1435-1452.
10. Taylor PN, Wilkinson Hart IA, Khan MS, Slade-Sharman DE. Correction of footdrop due to multiple sclerosis using the STIMuSTEP Implanted Dropped Foot Stimulator. Int. 2016;18(5):239-247.
11. Downing A, Van Ryn D, Fecko A, Aiken C, McGowan S, Sawers S, et al. Effect of a 2-week trial of functional electrical stimulation on gait function and quality of life in people with multiple sclerosis. Int. 2014;16(3):146-152.
12. Martin KD, Polanski W, Schackert G, Sobottka SB. New therapeutic option for drop foot with the ActiGait Peroneal Nerve Stimulator--a technical note. World Neurosurg. 2015;84(6):2037-2042.
13. Street T, Singleton C. A clinically meaningful training effect in walking speed using functional electrical stimulation for motor-incomplete spinal cord injury. J Spinal Cord Med. 2018;41(3):361-366.
14. Miller L, Rafferty D, Paul L, Mattison P. A comparison of the orthotic effect of the Odstock Dropped Foot Stimulator and the Walkaide functional electrical stimulation systems on energy cost and speed of walking in Multiple Sclerosis. Disabil. 2014;17:17.
15. Sardaru DP, Matei D, Zaharia-Kezdi D, Pendefunda L. Effects of biofeedback versus switch-triggered functional electrical stimulation on sciatica-related foot drop. J Back Musculoskelet Rehabil. 2018;31(2):239-245.
16. Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017;358:j4008. http://www.bmj.com/content/bmj/358/bmj.j4008.full.pdf. Accessed 1800 Jan 1.
17. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. J Epidemiol Community Health. 1998;52(6):377-384.
18. Prenton S, Hollands KL, Kenney LPJ, Onmanee P. Functional electrical stimulation and ankle foot orthoses provide equivalent therapeutic effects on foot drop: A meta-analysis providing direction for future research. J Rehabil Med. 2018;50(2):129-139.
19. Dunning K, O'Dell MW, Kluding P, McBride K. Peroneal stimulation for foot drop after stroke: A systematic review. Am J Phys Med Rehabil. 2015;94(8):649-664.
20. Dujovic SD, Malesevic J, Malesevic N, Vidakovic AS, Bijelic G, Keller T, et al. Novel multi-pad functional electrical stimulation in stroke patients: A single-blind randomized study. NeuroRehabilitation. 2017;41(4):791-800.
21. Khurana SR, Beranger AG, Felix ER. Perceived exertion is lower when using a functional electrical stimulation neuroprosthesis compared with an ankle-foot orthosis in persons with multiple sclerosis: A preliminary study. Am J Phys Med Rehabil. 2017;96(3):133-139.
22. Taylor P, Humphreys L, Swain I. The long-term cost-effectiveness of the use of Functional Electrical Stimulation for the correction of dropped foot due to upper motor neuron lesion. J Rehabil Med. 2013;45(2):154-160.

Appendix 1 : Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Systematic Reviews

First author, Year, Country	Objectives Intervention Comparators Literature Search Strategy	Inclusion Criteria	Exclusion Criteria	Number of Studies Outcomes
Prenton,[18] 2018, UK	*"To compare the randomized controlled trial evidence for therapeutic effects on walking of functional electrical stimulation and ankle foot orthoses for foot drop caused by central nervous system conditions"* (p 129) FES AFO Literature searches were conducted using MEDLINE, CINAHL, Cochrane Central Register of Controlled Trials, REHABDATA, PEDro, NIHR Centre for Reviews and Dissemination, Scopus and clinicaltrials.gov were searched (date limit not reported)	RCTs comparing various FES and AFO for foot drop caused by central nervous system conditions in patients of all age	Studies not fulfilling inclusion criteria	7 RCTs (464 patients) (450 stroke, 14 cerebral palsy) Meta-analysis on: 10-m walking speed (m/sec) For all patients . at final assessment (weeks not reported) For stroke . at final assessment (weeks not reported) . at 4 to 6 weeks
Dunning,[19] 2015, US	*"The purpose of this systematic review was to summarize the effect of daily use of single-channel foot drop stimulation among persons with stroke"* (p 649) FES AFO Literature searches were conducted using PubMed/-Medline, CINAHL, EMBASE, PEDro, and Cochrane Library through May 16, 2014	RCTs comparing single-channel FES and AFO for foot drop in patients RCTs comparing FES and AFO for foot drop caused by stroke in patients of all ages	Studies not fulfilling inclusion criteria	6 RCTs (820 patients) Narrative review on: 10-m walking speed (m/sec) Timed Up and Go Modified Emory Functional Ambulation Profile PCI FMA BBS Quality-of-life (using SIS, SSQOL, the SF-36) Outcomes measured after 6 to 30 weeks

AFO = ankle foot orthosis; BFS = Body Function and Structures; BBS = Berg Balance Scale; FMA = Fugl-Meyer Assessment; FES = functional electric stimulators; MS = multiple sclerosis; PCI = physiologic cost index; SF-36 = 36-item Short Form Health Survey; SIS = Stroke Impact Scale, SSQOL = Stroke-Specific-Quality-of- Life-Scale

Table 3: Characteristics of Included Studies

First Author, Year, Country	Study Design Study Objectives	Interventions and Comparators	Patients	Main Outcomes
Clinical studies				
Dujovic,[20] 2017, Serbia, Spain	RCT *"To evaluate efficacy of additional novel FES system to conventional therapy in facilitating motor recovery in the lower extremities and improving walking ability after stroke"* (p 791)	FES (FESa)+ conventional rehabilitation Conventional rehabilitation (physiotherapy 60 minutes a day, 5 days a week, for 4 weeks)	16 stroke patients > 18 years old with foot drop and walk speed less than 0.4 m/s.	10-m walking speed (m/s) FMA BBS mBI Outcomes measured at baseline and after 4 weeks
Khurana,[21] 2017, US	Cross-over RCT (including 2 visits, each visit included 2 walk trials, 1 with the AFO and 1 with the FES, with at least a 1-hour rest break in between. Participants were randomly assigned to which device would be used first during study visit 1, and the reverse order was used for visit 2) *"This study investigates the direct comparison of energy cost, efficiency, and effort between an ankle-foot orthosis (AFO) and a functional electrical stimulation (FES) device for foot drop in ambulatory patients with multiple sclerosis*" (p 133)	FES (WalkAide) AFO	20 multiple sclerosis patients >18 years old with foot drop	10-m walking speed (m/s) Perceived exertion (using Borg Scale that measures the intensity level of physical activity) Walking speed Caloric expenditure Metabolic efficiency Outcomes measured after 2 visits

BBS = Berg Balance Scale; EDSS = Expanded Disability Status Scale; FES = functional electric stimulators; FMA = FugI-Meyer Assessment; FSS = Fatigue Severity Scale; mBI - Modified Barthel Index; RCT = randomized controlled trial;

Appendix 3: Critical Appraisal of Included Publications

Table 4: Summary of Critical Appraisal of Included Studies

First Author, Publication Year	Strengths	Limitations
Critical appraisal of included systematic reviews (evaluated with the AMSTAR II Checklist[16])		
Prenton[18]	• a priori design provided • independent studies selection and data extraction procedure in place • comprehensive literature search performed • list of included studies, studies characteristics provided • quality assessment of included studies provided and used in formulating conclusions • conflict of interest stated	• list of excluded studies not provided • assessment of publication bias not performed • variability in intervention and comparator device design may limit the generalizability of the comparison in the primary trials and subsequently in the review
Dunning[19]	• a priori design provided • independent studies selection and data extraction procedure in place • comprehensive literature search performed • list of included studies, studies characteristics provided • quality assessment of included studies provided and used in formulating conclusions • conflict of interest stated	• list of excluded studies not provided • assessment of publication bias not performed • variability in intervention and comparator device design may limit the generalizability of the comparison in the primary trials and subsequently in the review
Critical appraisal of included clinical trials (evaluated with the Downs & Black Checklist[17])		
Dujovic[20]	• randomized controlled trial • hypothesis clearly described • method of selection from source population and representation described • loss to follow-up reported • main outcomes, interventions, patient characteristics, and main findings clearly described • estimates of random variability and actual probability values provided • study had sufficient power to detect a clinically important effect	• patients not blinded to the treatment • generalizability limited to those who had experienced stroke with a mean walking speed less than 0.4 m/s at initial evaluation
Khurana[21]	• cross-over randomized controlled trial • hypothesis clearly described • method of selection from source population and representation described • loss to follow-up reported • main outcomes, interventions, patient characteristics, and main findings clearly described • estimates of random variability and actual probability values provided	• patients and evaluators not blinded to the treatment • sample size not calculated in order to have power to detect a clinically important effect

Appendix 4: Main Study Findings and Author's Conclusions

Table 5: Main Clinical Study Findings and Authors' Conclusions

Main Study Findings	Authors' Conclusions
Stroke-Related Foot Drop	
Prenton[18] (Systematic Review/Meta-analysis)	
Difference in 10-meter walking speed between FES and AFO after 4 to 6 weeks of use (MD, 95% CI) *For all patients* (450 stroke patients and 14 cerebral palsy patients) At final assessment (data from 6 trials) 0.02; –0.03, 0.06; *P* = 0.46 *For stroke patients* At final assessment (data from 6 trials) 0.02; –0.03, 0.07; *P* = 0.54 At 4 - 6 weeks (data from 5 trials) 0.03; –0.06, 0.12; *P* = 0.49	*"This meta-analysis shows, for the first time, that FES and AFO are statistically proven to have the same therapeutic effect on walking speed in CNS foot drop. This effect has also specifically been shown to occur for foot drop caused by stroke and is observed after 4–6 weeks' use*" (p 137)
Dunning[19] (Systematic Review)	
Difference between FES and AFO after 6 to 30 weeks of use (narrative review; no meta-analysis done): 10-meter walking speed (from 6 trials): not statistically significant Timed Up and Go (from 3 trials), modified EFAP (from 2 trials), lower extremity FMA (from 2 trials): not statistically significant PCT (from 3 trials): statistically significant in favour of FES in 1 trial, and not significant in 2 trials BBS between FES and AFO (from 2 trials): statistically significant in favour of FES in 1 trial, and not significant in 1 trial Participant preference (from 2 trials): more patients preferred FES over AFO (no statistical significance reported)	*"Over 6 to 30 wks of use, FDS and AFO are effective and equivalent for increasing gait speed in persons with stroke and drop foot"* (p 662)
Dujovic[20] (RCT)	
Difference between FES plus conventional rehabilitation and rehabilitation alone after 4 weeks of use: 10-meter walking speed: statistically significant in favour of FES (*P* = 0.022) FMA, BBS, MI: not statistically significant	"*The findings suggest that novel FES therapy combined with conventional rehabilitation is more effective on walking speed, mobility of the lower extremity, balance disability and activities of daily living compared to a conventional rehabilitation program only*" (p 791)
Multiple Sclerosis-Related Foot Drop	
Khurana[21] (Cross-Over RCT)	
Difference between FES and AFO after 2 cross-over visits Perceived exertion (MD; 95% CI): statistically significant in favour of FES (*P* = 0.01) Walking speed, EDSS, FSS , FEScale: not statistical significant	*"Analysis of data collected during this 2-visit crossover randomized controlled trial showed that the majority of persons using the FES device reported less perceived exertion during both visits, than when using an AFO. All other primary and secondary outcome measures did not significantly differ by device across study sessions* (p 138)

95% CI = 95% confidence interval; AFO = ankle foot orthosis; BBS = Berg Balance Scale; BI = Barthel Index; FES = functional electric stimulators; FEScale = falls efficacy scale; EFAP = Modified Emory Functional Ambulation Profile; FMA = Fuji Meyer Assessment; MD = mean difference; PCT = physiologic cost test